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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,819	04/30/2001	Tomoko Nakayama	P107424-00027	9941

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EXAMINER

SAKELARIS, SALLY A

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

<b>Application No.</b> 09/843,819	<b>Applicant(s)</b> NAKAYAMA ET AL.	
<b>Examiner</b> Sally A Sakelaris	<b>Art Unit</b> 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a)  The period for reply expires 3 months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

- 1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
- 2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

- 3.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
- 4.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
- 5.  The a)  affidavit, b)  exhibit, or c)  request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
- 6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
- 7.  For purposes of Appeal, the proposed amendment(s) a)  will not be entered or b)  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-11.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

- 8.  The drawing correction filed on \_\_\_\_\_ is a)  approved or b)  disapproved by the Examiner.
- 9.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
- 10.  Other: \_\_\_\_\_

  
CARLA J. MYERS  
PRIMARY EXAMINER

Continuation of 2. NOTE: The proposed amendment extensively modifies the claims and as a result will not be entered. The recitation of "nucleic acid inclusion body" raises issues under 112 2<sup>nd</sup> paragraph, while "without extracting and purifying said nucleic acid from said nucleic acid inclusion body" include new limitations that raise issues concerning new matter and would require a new search of the prior art.

Continuation of 5. does NOT place the application in condition for allowance because: The applicant believes that amendments to the claims have put the application in condition for allowance. However, the rejections are being maintained. Applicant's arguments filed 2/24/2004 and 8/27/2004 have been fully considered but they are not persuasive. Applicant asserts that their amended recitation of "a living body-derived sample itself or the living body-derived sample itself is added to the amplification reaction solution" is not taught or suggested by Ivanov et al. The phrase "intracellular level body comprising nucleic acids from a living body derived sample itself" is considered to include nucleic acids which are purified/isolated from the living body-derived sample. The term "derived" means that the material from the living body sample may be further modified in some manner. An "intracellular level body" includes genomic nucleic acids, and is not limited to, for example, an intact, unmodified cell or an intact, unmodified cellular organelle. Further, it is noted that the specification at page 4 states that "the term 'itself' means that no special pretreatment is required". However, this recitation does not specifically exclude pretreatment. Rather, the recitation indicates that it is not essential to pretreat the sample. Thereby, these teachings in the specification indicate that pretreatment may occur, but it is not essential. Accordingly, it is maintained that the claims as written are inclusive of methods of adding nucleic acids to the amplification reaction containing glycerol and ammonium sulfate, as is taught in the method of Ivanov.

In summary, as stated in the Final action, dated May 5, 2004, the examiner finds the remaining traversals not convincing as it is maintained that the applied art rejections still stand.

Furthermore, the remaining rejections are also maintained for reasons of record in view of the non-entry of after final amendment